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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,096	06/28/2001	Avi J. Ashkenazi	P1134R2C2	3212

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GENENTECH, INC.
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EXAMINER

KAUFMAN, CLAIRE M

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/896,096

Applicant(s)

ASHKENAZI ET AL.

Examiner

Claire M. Kaufman

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-39 and 67-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30-39 and 85-89 is/are allowed.
- 6) ☒ Claim(s) 67-77 and 79-84 is/are rejected.
- 7) ☒ Claim(s) 78 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>13</u> . | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

The amendment filed 3/21/03 has been entered.

Drawings

The formal drawings submitted 3/21/03 are accepted by the Examiner.

Response to Arguments

The objection to claim 77 is withdrawn in view of Applicants' arguments.

The rejection of claims 67 and 75 under 35 USC 112, second paragraph, is withdrawn in view of the amendment to the claims.

The rejection of claims 67-77 and 79-84 under 35 USC 102(e) as anticipated by Emery et al. (US 5,885,800) is withdrawn because the patent is not enabling for antibodies which bind DcR3 (TR4) *and also* inhibit binding of Fas ligand to the DcR3 receptor because the ligand for TR4 necessary to make/screen such antibodies was not specifically identified. Therefore, the patent is not available as prior art for the present claims and the rejection has been withdrawn.

However, upon further consideration, a new ground(s) of rejection is made in view of Gentz et al. US 2002/0150583 A1, cited by Applicants in IDS paper #13. See rejection below.

Priority

It is maintained that the instant application receives an effective filing date for the instant claimed invention of provisional application priority 60/094,640, filed 07/30/98, for the reasons set forth in the previous Office action on p. 4.

Applicant's arguments are moot in view of the removal of Emery as 102(e) art.

Gentz et al. (US 2002/015058), relied on below, receives an effective filing date of its priority application US 09/006,352, filed January 13, 1998. Note that for the purpose of 35 USC 102(e), Gentz et al. does not receive priority to US provisional 60/035,496, filed January 14, 1997.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 67-77 and 79-84 are rejected under 35 U.S.C. 102(e) as being anticipated by Gentz et al. (US 2002/0150583 A1, cited by applicants in paper #13).

Gentz et al. teach the TNFR-6 α polypeptide (SEQ ID NO:2) which has a sequence identical to the DcR3 polypeptide (SEQ ID NO:1) of the instant application. Also taught are antibodies that bind and are agonistic or antagonistic anti-TNFR-6 α antibodies, including antibody fragments, monoclonals, polyclonals, recombinant, chimeric and human antibodies, as well as methods of making the antibodies and antibody-producing host cells (p. 39, [0240] through p. 41, [0249], see also [0278]-[0279]). TNFR-6 α is shown to bind Fas ligand in, for example, Figures 7A-B. The antagonistic antibodies include those that block the binding of TNFR-6 α with not only Fas ligand, but also inherently LIGHT, absent evidence to the contrary. Uses for such antibodies are listed and include *in vivo* and *in vitro* imaging of TNFR-6 α -containing cells (e.g., [0381] and [0383]). Also, TNFR-6 α antagonists, which necessarily include antibodies, are those that inhibit growth of cancers ([0371] and [0396]).

Prior Art

The art made of record and not relied upon is considered pertinent to applicant's disclosure. US 2002/0068064A1 is not prior art, but teaches antibodies to DcR3 and claims anti-DcR3 antibodies produced by specific hybridomas.

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Conclusion

Claims 30-39 and 85-89 are allowable.

Claim 78 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

July 31, 2003